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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,412	04/01/2008	Carlos Manuel Miyares Cao	LEX P37	5240
28752 7590 07/07/2011 LACKENBACH SIEGEL, LLP LACKENBACH SIEGEL BUILDING 1 CHASE ROAD SCARSDALE, NY 10583				
EXAMINER				
VAKILI, ZOHREH				
ART UNIT		PAPER NUMBER		
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/567,412

**Applicant(s)**

MIYARES CAO ET AL.

**Examiner**

ZOHREH VAKILI

**Art Unit**

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 February 2011.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 10-14 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

**Claims 10-14 are presented for examination.**

A request for continued examination under 37 C.F.R. 1.114, including the fee set forth in 37 C.F.R. 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 C.F.R. 1.114, and the fee set forth in 37 C.F.R. 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 C.F.R. 1.114. Applicant's submission filed February 23, 2011 has been received and entered into the present application. Claims 10-14 are pending and are herein examined on the merits.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

"The primary purpose of this requirement of definiteness of claim language is to ensure that the scope of the claim is clear so the public is informed of the boundaries of what constitutes infringement of the patent. A secondary purpose is to provide a clear measure of what applicants regard as the invention so that it can be determined whether the claimed invention meets all the criteria for patentability and whether the

specification meets the criteria of 35 U.S.C. 1 12, first paragraph with respect to the claimed invention." (MPEP 2173).

The term "an 80% Hydro alcohol" is not clear what Applicant is referring to, which renders the claims indefinite. The term is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and thus one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Because the term "an 80% hydro alcohol" would invite subjective interpretations of whether "an 80% hydro alcohol" would mean 80% H<sub>2</sub>O and 20% alcohol or "an 80% hydro alcohol" would mean 80% alcohol and 20% H<sub>2</sub>O. Further, it is not clear 80% of what is it being referred to w/v, v/v.

***Claim Rejections - 35 USC § 112 1<sup>st</sup> Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-14 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is drawn to compositions comprising 80% hydro alcohol the claims do not indicate what distinguishing attributes are concisely shared by the members of the very broad genus comprising 80% hydro-alcohol, and which provide for the function claimed, of stimulating melanin in skin. Specifically which hydro-alcohol and proline would form the claimed composition. The specification and claims do not describe elements which are essential to the genus comprising such. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between members of the genus is permitted. Concise structural features that could distinguish structures or compounds within this genus from others are missing from the instant disclosure. The specification fails to teach or adequately describe a representative number of species in this broad genus such that the common attributes or characteristics concisely identifying members of the genus are exemplified, and, because the claimed genus is so highly variable, the description provided is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus claimed. Thus, Applicant was not in possession of the claimed genus.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having

ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slavtcheff et al. (USPN 5484597), in view of Raghupathi et al. (USPN 6696417 B1), further in view of, further in view of Yoneyama et al. (USPN 5015469) and Chevalier et al. (US Pub. No. 2002/0197289).

Slavtcheff et al. teach a cosmetic microemulsion composition that includes about 1 to about 99% water and about 1 to about 99% of a C1-C4 alkanol (see col. 1, lines 50-55). The hydroalcoholic microemulsion composition can be applied on skin (see col. 2, lines 37-38).

Raghupathi et al. teach a cosmetic for skin/hair darkening composition comprising from 0.1% to 10% (col. 1, lines 60-62) and preferably 0.5 to 5.0% by weight of the peptide (col. 2, lines 25-27). The amino acid residues forming the peptide sequence can be naturally occurring or synthetic. The peptide sequence must

comprise a proportion of the amino acids (col. 2, lines 6-10). The amino acid can be chosen from any one of alanine, isoleucine, leucine, methionine, phenyl alanine, proline, tryptophan or valine. The targeting molecule is preferable a peptide (col. 2, lines 16-19). The vehicle which forms part of the cosmetic composition is one or more substances which are compatible with the polyamino acid sequence and which are also cosmetically acceptable in that they will not harm the skin/hair. The vehicles that can be used in the compositions are carriers, and liquids such as emollients, and solvents. Also simple vehicles such as alcohol, may also be used (col. 2, lines 41-50).

Yoneyama et al. teach a water in oil emulsified composition. The total amount of water and the polyhydric alcohol formulated may be about 5 to 80% by weight in the water- and polyhydric alcohol-in-oil type emulsified composition (col. 7, lines 45-47). In the W/O type emulsion it is also possible to formulate amino acids and salts thereof, humectants, pigments, etc., if desired, within the range which does not impair the effect of the composition. Examples of the above amino acids may include hydroxyproline, proline, etc., which comprise a L-derivative. Particularly preferred among the above are L-hydroxyproline, and L-proline (col. 7, lines 50-68).

Chevalier et al. teach a cosmetic composition in treatment of the skin (abstract). The active agents may be chosen, for example, from moisturizers, free-radical scavengers, bleaching agents, etc., and mixtures thereof. [0041]. Useful moisturizers include polyols, sorbitol, mannitol, and mannitol; amino acids; and mixtures thereof [0042]. The composition of the invention may comprise one or more active agents, of

the same category or of different categories. The amount of active agent(s) in the composition depends on the active agent used and on the purpose of the composition. The active agent(s) must be present in an effective amount that is to say in an amount that is sufficient to achieve the desired aim, which is to improve the appearance of the skin. The amount of active agent(s) in the composition may range, for example, from 0.0001% to 30% by weight, and even better still from 0.5% to 10% by weight relative to the total weight of the composition [0152]. The compositions may be in any form, including those conventionally used for topical application, and especially in the form of aqueous, aqueous-alcoholic or oily solutions, oil-in-water (O/W) or water-in-oil (W/O) or multiple (W/O/W or O/W/O) emulsions, aqueous or oily gels, liquid, pasty or solid anhydrous products [0175].

It would have been obvious to have used the teachings of the above references to formulate a composition comprising L-proline and a hydro alcohol in a solution.

One would have been motivated to create such formulation because Slavtcheff et al. teach a cosmetic micro emulsion composition that includes about 1 t about 99% water and about 1 t about 99% of a C1-C4 alkanol. The hydroalcoholic microemulsion composition can be applied on skin. Raghupathi et al. teach a cosmetic for skin/hair darkening composition comprising proline in vehicles such as emollients, solvents and also alcohol. Chevalier et al. teach a cosmetic composition in treatment of the skin and the amount of active agent(s) amino acid, proline, in the composition may range from 0.5% to 10% by weight. The compositions may be in any form such as aqueous-alcoholic solutions. Therefore, one of ordinary skill in the art would have been



motivated to use the formulation taught by the above references. It will be apparent to one of ordinary skill in the art that many changes and modifications can be made thereto without departing from the spirit or scope of the appended claims. The determination of the alcoholic excipient to the active ingredient are well within the level of one having ordinary skill in the art, and the artisan would be motivated to determine optimum amounts to get the maximum effect of the drug while minimizing adverse or unwanted side effects or even undesirable stability issues.

The determination of the optimum ranges for the presently claimed active agent(s) would have been a matter well within the purview of one of ordinary skill in the art. Applicant's attention is further drawn to MPEP at §2144.05, which states, "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages...Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

In re Kerkhoven (205 USPQ 1069, CCPA 1980) states that "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the same purpose: the idea of combining them flows logically from their having been individually taught in the prior."

One of ordinary skill in the art would have been motivated to combine the above references and as combined teach and suggest the invention as claimed. Thus the

claimed invention was within the ordinary skill in the art to make and use at the time the claimed invention was made and was as a whole, *prima facie* obvious.

Thus, the claimed invention was within the ordinary skill in the art to make and use at the time it was made and was as a whole, *prima facie* obvious over the cited arts.

Finally, one would have a reasonable expectation of success given that the above references provide a detailed blueprint for formulating a composition comprising L-proline and hydro-alcohol and the steps of which are routine to one of ordinary skill in the art.

### ***Response to Arguments***

Applicant's remarks and arguments are moot in view of new grounds of rejection.

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Lundgren, can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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Zohreh Vakili

Patent Examiner  
1629

June 11, 2011

/Jeffrey S. Lundgren/

Supervisory Patent Examiner, Art Unit 1629